HED DOC. NO. 013735

September 13, 1999

MEMORANDUM

SUBJECT: ***OXAMYL*** **-** Report of the FQPA Safety Factor Committee

FROM: Brenda Tarplee, Executive Secretary
FQPA Safety Factor Committee
Health Effects Division (7509C)

THROUGH: Ed Zager, Chairman
FQPA Safety Factor Committee
Health Effects Division (7509C)

TO: Diana Locke, Risk Assessor
Reregistration Branch 2
Health Effects Division (7509C)

PC Code: 103801

The FQPA Safety Factor Committee met on August 30, 1999 to evaluate the hazard and exposure data for oxamyl and recommended that the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996) be removed (1x) in assessing the risk posed by this chemical.

I. HAZARD ASSESSMENT

(*Memorandum:* G. Reddy to D. Locke dated August 31, 1999)

A. Adequacy of the Toxicology Database

The toxicology database for oxamyl is adequate according to the Subdivision F Guideline requirements for a food-use chemical.

B. Determination of Susceptibility

The HIARC concluded that the data provided no indication of increased susceptibility in rats or rabbits from *in utero* and/or postnatal exposure to oxamyl:

> In the developmental toxicity study in rabbits, no developmental toxicity was seen at the highest dose tested. In the two-generation reproduction study in rats, decrease in pup viability and decreased pup body weights observed at the highest dose tested is of no concern due to significantly decreased maternal body weights during the lactation.
>
> The apparent quantitative difference in susceptibility demonstrated in the prenatal developmental toxicity study in rats (developmental NOAEL of 0.2 mg/kg is quantitatively lower than the maternal NOAEL of 0.5 mg/kg/day) was not a true indication of increased susceptibility since a decrease in maternal body weight (not statistically significant) also occurred at the 0.5 mg/kg/day dose (developmental LOAEL). In addition, at higher doses the decreases in fetal body weights corroborated with decreases in maternal body weights and food consumption and clinical signs with increasing doses. Thus the data indicated that the decreases in fetal weights are not an indication of increased susceptibility, but occurred due to maternal toxicity.

C. Determination of Developmental Neurotoxicity Study

The HIARC determined that a developmental neurotoxicity study with oxamyl is not required.

II. EXPOSURE ASSESSMENTS

A. Dietary (Food) Exposure Considerations

(*Correspondence:* G. Reddy to E. Zager dated August 19, 1999)

Permanent tolerances are currently established for the sum of the residues of the insecticide oxamyl and its oxime metabolite calculated as oxamyl in or on various commodities at levels ranging from 0.1 to 10 ppm. Many of these commodities are considered to be highly consumed by infants and children, such as apples, oranges, pears, and soybeans. Residues have not been found to transfer to meat, milk, poultry, or eggs. There are Codex MRLs for oxamyl and its oxime metabolite (combined) for several commodities.

Data sources for oxamyl include residue data from field trial studies for registered crops and monitoring data for many commodities from FDA and USDA's Pesticide Data Program (PDP). Monitoring data reveal non-detectable residues or very low level residues for most commodities. A Qualitative Usage Analysis was provided to HED by the Biological and Economic Analysis Division which includes percent crop treated information for oxamyl.

Dietary food exposure analyses will be performed to estimate the acute and chronic dietary risk for oxamyl using the Dietary Exposure Evaluation Model (DEEM). DEEM combines pesticide residue data with food consumption data to estimate dietary (food only) exposure. Both the chronic and acute analyses are expected to be refined using anticipated residue estimates based on available monitoring data as well as percent crop treated information. The result is a more realistic estimate of the dietary exposure expected from the application of oxamyl to food commodities.

B. Dietary (Drinking Water) Exposure Considerations
(*Correspondence:* L. Libelo to B. Tarplee, dated August 29, 1999.)

The environmental fate database is adequate to characterize drinking water exposure. Parent oxamyl has a low affinity for adsorption, and is highly mobile in a variety of soils. Field dissipation and prospective groundwater studies show that both oxamyl and oxime are capable of leaching through the soil.

Tier I Estimated Environmental Concentrations (EECs) for oxamyl were calculated using GENEEC (surface water) and SCIGROW (groundwater) models for use in the human health risk assessment. The maximum application rate for oxamyl (12 lb a.i. per acre per year - pineapple scenario) was used to calculate surface water and groundwater EECs which result in upper-bound estimates of the concentrations that might be found in surface and groundwater due to the use of oxamyl in vulnerable areas.

Monitoring data are available and the studies generally suggest that oxamyl in not a major surface water or groundwater contaminant. In an on-going Prospective Groundwater Monitoring Study in North Carolina, parent oxamyl was detected in groundwater in concentrations up to about 4 ppb and the oxime degradate was detected at concentrations up to 4.5 ppb. These data match the ground water modeling output.

C. Residential Exposure Considerations
(*Correspondence:* G. Reddy to E. Zager dated August 19, 1999)

There are currently no registered residential (non-occupation) uses for oxamyl.

III. SAFETY FACTOR RECOMMENDATION AND RATIONALE

A. Recommendation of the Factor

The Committee recommended that the FQPA safety factor for protection of infants and children (as required by FQPA) be **removed (1x).**

B. Rationale for Removing the FQPA Safety Factor

The Committee concluded that the safety factor could be removed for oxamyl because:

1. The toxicology database is complete for FQPA assessment;

2. The HIARC concluded that the toxicity data provide no indication of increased susceptibility of young rats or rabbits to oxamyl;

3. The HIARC determined that a developmental neurotoxicity study is not required;

4. The exposure assessments will not underestimate the potential dietary (food and drinking water) exposures for infants and children from the use of oxamyl; and

5. There are currently no residential (non-occupational) uses of oxamyl.